UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

UNITED STATES OF AMERICA,	)	
	)	
v.	)	Docket No. 2:22-cr-00132-NT
	)	
MERIDETH C. NORRIS,	)	
	)	
Defendant.	)	

ORDER ON DEFENDANT'S MOTION TO SUPRESS PATIENT RECORDS

Before me is Defendant Merideth C. Norris's motion to suppress evidence obtained pursuant to court orders for the disclosure and use of patient records (ECF No. 71). For the reasons stated below, the Defendant's motion is **DENIED**.

BACKGROUND

The Defendant, Merideth C. Norris, D.O., is a licensed medical doctor in Maine. *See* Hr'g Tr. Day 1 51:1–51:3 (ECF No. 140). She has a solo practice in Kennebunk, Merideth C. Norris P.A., which does business as "Graceful Recovery," (the "**Practice**"), and she also practices at Savida Health, CAP Quality Care, and Enso, LLC. *See* Hr'g Tr. Day 1 51:15–51:24, 57:22–58:1, 65:4–65:10.

Around June of 2022, the New England Prescription Opioid Strike Force (the "**Strike Force**") began investigating Dr. Norris to determine whether she had violated the Controlled Substances Act by prescribing controlled substances outside the usual course of professional practice and with no legitimate medical need. Hr'g Tr. Day 1 42:16–43:12; *see* 21 U.S.C. § 841. As part of its investigation, on August 17, 2022, the Government applied for an order authorizing the disclosure and use of

patient records from the Practice and from Savida Health pursuant to the Public Health Service Act (the "**Act**") and its regulations. Docket No. 2:22-mc-00179-KFW, ECF No. 2; Gov't's Hr'g Ex. 16; Def.'s Hr'g Ex. 20; *see* 42 U.S.C. § 290dd-2(b)(2)(c); 42 C.F.R. § 2.66.

I. The Act and Its Regulatory Scheme

The Act protects the confidentiality of "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with" a substance abuse treatment program. 42 U.S.C. § 290dd-2(a). Qualifying patient records may be disclosed or used only as the regulations[1] permit and "may not otherwise be used or disclosed in any . . . criminal . . . proceedings conducted by any Federal . . . authority." 42 C.F.R. § 2.13(a). The regulations restrict both "disclosure" and "use" of the records. They restrict "use and disclosure" if the records (1) "[w]ould identify a patient as having or having had a substance use disorder" and (2) include drug or alcohol abuse information obtained by a federally assisted alcohol or drug abuse program. *Id.* § 2.12(a)(1)(i)–(ii). The regulations prohibit "use" of the records to

[1] The Public Health Service Act directs the Secretary of the Department of Health and Human Services ("**HHS**") to "prescribe regulations to carry out the purposes of [the Act]. . . . including procedures and criteria for the issuance and scope of orders" authorizing disclosure. 42 U.S.C. § 290dd-2(g). On February 16, 2024, HHS issued a final rule to modify its regulations to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Confidentiality of Substance Use Disorder (SUD) Patient Records, 89 Fed. Reg. 12472, 12472 (Feb. 16, 2024) (to be codified at 42 C.F.R. pt. 2). The modified regulations became effective on April 16, 2024, and persons subject to them must comply with the requirements by February 16, 2026. Confidentiality of Substance Use Disorder (SUD) Patient Records, 89 Fed. Reg. at 12472. The parties agree that, at least for the purposes of the present motion, the old regulations apply.

"initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient."[2] *Id.* § 2.12(a)(2).

Records may be disclosed only in limited circumstances, one of which is "[i]f authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor." 42 U.S.C. § 290dd-2(b)(2)(C). When the Government seeks qualifying patient records to investigate or prosecute a substance abuse "program" or a "person holding the records" it must obtain a use and disclosure order. *See* 42 C.F.R. § 2.66. In order to get such an order, "good cause" must be shown. *Id.* §§ 2.66(c), 2.64(d). This requires two findings: (1) that "[o]ther ways of obtaining the information are not available or would not be effective," and (2) that "[t]he public

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[2] The regulations contain some definitions that help clarify the scope of the confidentiality protections:

> - **Diagnosis** means any reference to an individual's substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment.
> - **Disclose** means to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.
> - **Patient** means any individual who has applied for or been given diagnosis, treatment, or referral for treatment for a substance use disorder at a part 2 program. . . . This definition includes both current and former patients. . . .
> - **Records** means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts) . . . .
> - **Treatment** means the care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient.

42 C.F.R. § 2.11.

interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services." *Id.* §§ 2.64(d), 2.66(c).

The regulations state that notice must be provided for orders authorizing disclosure for noncriminal purposes. *Id.* § 2.64. For criminal investigations into a program or the person holding the records, the regulations contain a provision entitled "Notice not required." *Id.* § 2.66(b). Under 42 C.F.R. § 2.66(b), a court may issue an order without notice, provided that the program, the person holding the records, and any patient whose records are disclosed "be afforded an opportunity to seek revocation or amendment of that order" upon "implementation" of that order. *Id.*; *United States v. Shinderman*¸ 432 F. Supp. 2d 149, 153–54 (D. Me. 2006) (finding that implementation occurs when patient records are made available to prosecutors).

Any order allowing use and disclosure must also require the deletion of patient-identifying information from documents made available to the public, 42 C.F.R. § 2.66(d)(1), and must limit disclosure to the parts of the patient records that are essential to fulfill the objectives of the order. *Id.* § 2.64(e)(1). In addition, information obtained pursuant to an order cannot be used to criminally investigate or prosecute a patient. *Id.* § 2.66(d)(2).

The regulations differentiate between ordinary information and "confidential communications" contained within qualifying patient records.[3] The regulations provide, in pertinent part:

[3] "Because the regulations treat different types of information dissimilarly, . . . the information must be differentiated and categorized as either 'confidential communications' or as something other than confidential communications." *In re Aug., 1993 Regular Grand Jury (Hosp. Subpoena)*, 854 F. Supp. 1380, 1384 (S.D. Ind. 1994). Pre-1987, "the regulations explicitly denominated this latter

> A court order under the regulations in this part may authorize disclosure of confidential communications made by a patient to a part 2 program in the course of diagnosis, treatment, or referral for treatment only if:
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> (1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties; [or]
>
> (2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect . . . .

Id. § 2.63(a). In order to obtain "confidential communications," the Government must thus establish both that (1) good cause for an order exists, and (2) one of the preconditions set out in section 2.63(a) exists. *In re Aug., 1993 Regular Grand Jury (Hosp. Subpoena)*, 854 F. Supp. 1380, 1384 (S.D. Ind. 1994).

The Act contemplates penalties for violations. 42 U.S.C. § 290dd-2(f). "Under 42 U.S.C. 290dd-2(f), any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with Title 18 of the U.S. Code." 42 C.F.R. § 2.3. Finally, "[b]ecause there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute . . . ." 42 C.F.R. § 2.2(b)(3).

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category as 'objective data,' consisting of all information regarding a patient's treatment in a program except 'communications by a patient to personnel of the program.' " *Id.* (quoting 42 C.F.R. § 2.63(a) (amended 1987)). The 1987 amendment "inverted the phrasing of the regulations" so they are "now positively drafted in terms of 'confidential communications.' " *Id.*

II. The Patient Records Orders

On August 25, 2022, the Magistrate Judge issued an *ex parte* order ("**Patient Records Order**") granting the Government's request for authorization to use and disclose Dr. Norris's patient records from the Practice and Savida Health. Order for Disclosure and Use of Patient Rs. (Docket No. 2:22-mc-00179-KFW, ECF No. 5). The Patient Records Order was issued based on the Government's asserted need for records to "criminally or administratively investigate or prosecute a program or the person holding records or agents or employees of a program involved in the treatment of drug-addicted patients with Suboxone and/or Subutex." Patient Rs. Order 1. The Magistrate Judge found that good cause existed because other ways of obtaining the information were not available or would not be effective, and the public interest and need for the disclosure outweighed the potential injury to patients, the physician-patient relationship, and the treatment services. Patient Rs. Order 1–2. The August 25, 2022 Patient Records Order contained no expiration date. The Government did not seek authority for the disclosure of confidential communications.

The Patient Records Order required the Government to limit disclosure of the records to the parts that were essential to fulfill its objective and to those persons whose need for the information was the basis of the order. Patient Rs. Order 2. It further required the Government to delete patient-identifying information, to refrain from using the information to investigate or prosecute patients, and to disclose the Patient Records Order to the appropriate party "each time it is implemented" so the party could seek to revoke or amend it. Patient Rs. Order 2–3. On October 14, 2022, the Magistrate Judge amended the Order to also cover patient records from CAP

Quality Care and Enso, LLC (the "**Amended Patient Records Order**").[4] Am. Order for Disclosure and Use of Patient Rs. (Docket No. 2:22-mc-00179-KFW, ECF No. 11). The Amended Patient Records Order was granted for a period of six months commencing on August 25, 2022, the date of the original Patient Records Order. Am. Patient Rs. Order 2.

III. Implementation of the Patient Records Orders

After the Government received the Patient Records Orders, the investigation proceeded apace. On September 23, 2022, the Government sought, received, and executed a search warrant ("**Elation Warrant**") for Dr. Norris's patient records held by her electronic medical records vendor. Elation Health, Inc. Appl. for a Warrant (Docket No. 2:22-mj-00166-KFW, ECF No. 1); Gov't's Hr'g Ex. 17, at 26–28; Def.'s Hr'g Ex. 1, at 26–28. After Dr. Norris was indicted on October 20, 2022, the Government applied for a second search warrant for patient records at Dr. Norris's practice. Appl. for a Warrant (Docket No. 2:22-mj-00198-NT, ECF No. 1). The application was granted on October 25, 2022, and the warrant ("**Practice Warrant**") was executed that same date. *See* Docket No. 2:22-mj-00198-NT, ECF Nos. 2, 5. The affidavits in support of both warrants noted the existence of the Patient Records Orders. *See* Docket No. 2:22-mj-00166-KFW, ECF No. 1-1, Docket No. 2:22-mj-00198-NT, ECF No. 1-1.

[4] The Magistrate Judge made the same findings for support of the Amended Patient Records Order and included the same restrictions on the use and disclosure of patient records in the Amended Order. *Compare* Am. Order for Disclosure and Use of Patient Rs. 1–3 (Docket No. 2:22-mc-00179-KFW, ECF No. 11), *with* Order for Disclosure and Use of Patient Rs. 1–3 (Docket No. 2:22-mc-00179-KFW, ECF No. 5). I refer to the two orders collectively as the Patient Records Orders or the Orders.

Dr. Norris was not given notice of the Patient Records Orders until after she was served with a subpoena for records, and she moved to quash the subpoena in late 2022. Mot. to Quash (ECF No. 28); Am. Mot. to Quash (ECF No. 31). In December of 2022, while litigating the motion to quash, the Government notified the Defendant of the Amended Patient Records Order for the first time.[5] Mot. to Suppress for Violation of Def.'s Fourth and Fifth Amendment Rights and Violation of Ct. Order for Disclosure and Use of Patient Records and Am. Order ("**Mot. to Suppress**") 13, 22–23 (ECF No. 71) & Ex. B; Gov't's Opp'n to Def.'s Mot. to Suppress ("**Gov't's Opp'n**") 9–10 (ECF No. 86).

DISCUSSION

Dr. Norris faces a superseding indictment charging her with seventeen counts of distribution of a controlled substance relating to seventeen prescriptions she made to five different patients allegedly in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2. Superseding Indictment 2–3 (ECF No. 62). The Defendant seeks to suppress the records of the five patients on the grounds that the Government obtained the records in violation of her Fourth and Fifth Amendment rights, the Act and its regulatory scheme, and the Patient Records Orders. Mot. to Suppress 1, 12–13. I begin by considering which side bears the burden of proof. I next address the Defendant's arguments that the Government violated the Act and its regulations and the Patient Records Orders. I then consider whether the statutory and regulatory violations

[5] The Defendant asserts that she received a copy of the original Patient Records Order on March 2, 2023. Mot. to Suppress 23 n.17.

amount to constitutional violations, and finally I address the Defendant's argument that I should use the Court's inherent supervisory powers to suppress evidence taken in violation of the Patient Records Orders.

I. Burden of Proof

The parties agree that the Defendant bears a threshold burden of proving that she had a legitimate expectation of privacy as a prerequisite to challenging the constitutionality of a search. *United States v. Lam Ly*, 94 F. Supp. 3d 5, 12 n.3 (D. Mass. 2015) (citing *United States v. Sánchez*, 943 F.2d 110, 113 n.1 (1st Cir. 1991)). The Government does not contest that Dr. Norris has standing to make her Fourth Amendment argument. *See Mancusi v. DeForte*, 392 U.S. 364, 369 (1968) ("It has long been settled that one has standing to object to a search of his office, as well as of his home.").

Where, as here, the Defendant is contesting a seizure of records that was "effected pursuant to a warrant, the defendant bears the burden of proving its illegality." *United States v. Adams*, 221 F. Supp. 2d 18, 22 n.4 (D. Me. 2002); *see also Lam Ly*, 94 F. Supp. at 13 ("[D]efendants bear the burden of showing by a preponderance of the evidence that warranted search was unlawful."); *United States v. Daprato*, No. 2:21-cr-00015-JDL-4, 2022 WL 1303110, at *4 (D. Me. May 2, 2022) ("Where, as here, a search is conducted pursuant to a warrant, the burden falls to the defendant to show the absence of probable cause by a preponderance of the evidence."). The Defendant does not concede that she has this burden, but she offers no authority or argument to persuade me that the Government bears the burden. I conclude, based on the above authority and the lack of any contrary argument, that

the Defendant bears the burden of establishing the illegality of the search and seizure of the patient records.

II. Violations of the Act, the Regulatory Scheme, and the Patient Records Orders

A. Whether the Records Are Subject to the Act

The Defendant takes the position that the records of the five patients at issue in the Superseding Indictment are all protected by the Act. Reply to Gov't's Opp'n to Def.'s Mot. to Suppress for Violation of Def.'s Fourth and Fifth Amendment Rights and Violation of Ct. Order for Disclosure and Use of Patient Rs. ("**Def.'s Reply**") 3–4 (ECF No. 96). The Government contends that "the patient files and other evidence seized pursuant to the two warrants and subpoenas[6] at issue (that which the government seeks to introduce at trial), are not substance-use-disorder patient records, and therefore, not subject to the heightened confidentiality protections." Gov't's Opp'n 11.

At the reopened suppression hearing, the Defendant offered into evidence Dr. Norris's records pertaining to the five patients that are the subject of the Superseding Indictment ("**Patient Records Exhibits**"). Def.'s Hr'g Exs. D1–D5. The Government contends that Dr. Norris was not treating any of these five patients for substance use disorder and that therefore the Act and the regulations do not apply. Gov't's Opp'n 12–15. But the Act's protections flow not just to patients who are presently in

6 Dr. Norris also seeks the suppression of records obtained pursuant to certain subpoenas. Mot. to Suppress for Violation of Def.'s Fourth and Fifth Amendment Rights and Violation of Ct. Order for Disclosure and Use of Patient Rs. And Am. Order ("**Mot. to Suppress**") 20 (ECF No. 71). Because the Government only plans to introduce records seized pursuant to the Elation Warrant, *see* Gov't's Opp'n to Def.'s Mot. to Suppress ("**Gov't's Opp'n**") 10 (ECF No. 86), I focus my analysis there.

treatment for substance use disorder. The Act applies to "any records which . . . [w]ould identify a patient as having or having had a substance use disorder . . . ." 42 C.F.R. § 2.12(a)(1)(i). A review of Defendant's Patient Records Exhibits allows me to conclude without difficulty that all five of the patient files contain records that "[w]ould identify a patient as having or having had a substance use disorder" and (2) include drug or alcohol abuse information obtained by a federally-assisted alcohol or drug abuse program.[7] 42 C.F.R. § 2.12(a)(1)(i)–(ii); *see, e.g.*, Def.'s Hr'g Ex. D1, at 422; Def.'s Hr'g Ex. D2, at 565; Def.'s Hr'g Ex. D3, at 1117; Def.'s Hr'g Ex. D4, at 1722; Def.'s Hr'g Ex. D5, at 176. The Defendant has established that at least some of the records in each of the five patient files comprising the Defendant's Patient Records Exhibits are subject to the Act.

B. Whether the Defendant Has Established Violations

The Defendant asserts that the Government, in seizing all of Dr. Norris's patient records, violated the Act and/or its regulations in three ways. First, the Defendant asserts that the Government seized records that were not essential to fulfill the object of the Patient Records Orders as required by 42 C.F.R. § 2.64(e)(1) and the Patient Records Orders. Mot. to Suppress 16. Second, the Defendant contends that the Government seized records that contained confidential communications in violation of 42 C.F.R. § 2.63, when it only had authority to seize "ordinary run-of-the-mill objective data." Mot. to Suppress 14. Third, the Defendant argues that the

[7] The parties agree that the Practice qualifies as a federally assisted alcohol or drug abuse program (a part 2 program). *See* Mot. to Suppress 9; Gov't's Opp'n 7–8 (ECF No. 86).

Government violated the notice requirements of 42 C.F.R. § 2.66(b). Mot. to Suppress 22. I address each of these alleged violations in turn.

1. Records Not Essential to Fulfill the Object of the Order

The Defendant argues that the Government took records that were not "essential to fulfill the object of this order" when it executed the warrants in violation of the Patient Records Order and 42 C.F.R. § 2.64(e)(1).[8] The records contained in the Defendant's Patient Records Exhibits were seized pursuant to the Elation Warrant, so I focus there. The affidavit in support of the application for the Elation Warrant referenced the Patient Records Order. As required by 42 C.F.R. § 2.64, the Patient Records Order directed the Government to: "limit disclosure to those parts of the patients' records that are essential to fulfill the objective of this order." Patient Rs. Order at 2. The objective of the Patient Records Order was to allow the Government access to records protected by the Act so that it could "criminally . . . investigate or prosecute a program or the person holding records or agents or employees of a program involved in the treatment of drug-addicted patients with Suboxone and/or Subutex." Patient Rs. Order 1. Because the Task Force took all of Dr. Norris's patient records when it executed the Elation Warrant, the Defendant contends that it took records well beyond those parts that were essential to fulfill the objective of the Patient Records Order.

[8] 42 C.F.R. § 2.64(e)(1) requires an order authorizing a disclosure to "[l]imit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order." 42 C.F.R. § 2.64(e)(1)

The problem with the Defendant's argument is that it conflates the scope of the Elation Warrant with the scope of the Patient Records Order. When it sought the Elation Warrant, the Government established probable cause to believe that Dr. Norris was prescribing opiates and other controlled substances without medical need and outside the usual course of professional practice in violation of 21 U.S.C. § 841. The Government was investigating Dr. Norris not just in her role treating patients with substance use disorder, but also in her roles as a pain specialist and primary care doctor. While the Patient Records Order allowed the Government to seize the records of patients with alcohol and substance use disorder, it did not mandate that the Government only seize records of patients with alcohol and substance use disorder regardless of any warrant authorizing a broader seizure.

The Elation Warrant gave the Government the right to seize all of Dr. Norris's patient records and to review them to determine whether they contained evidence of a violation of 21 U.S.C. § 841. The Defendant argued at oral argument that the Government should have only taken the patient files of patients who were prescribed narcotics. The Defendant has provided no authority and I know of none that would require the Government to narrow its search in such a way. The Government was allowed access under the warrants to all of Dr. Norris's patient records (with the possible exception of confidential communications as discussed below). Because the Government was not limited by the Elation Warrant to seizing records that were essential to fulfill the object of the Patient Records Order, the Defendant has not

established a violation of the Act, the regulations, or the Patient Records Orders on this basis.

2. Confidential Communications

The Defendant also argues that the Government violated the Act by seizing records that contained "confidential communications" that were not supported by the Patient Records Orders. In order to obtain disclosure of confidential communications, the Government would have had to establish, in addition to good cause, that "disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury."[9] 42 C.F.R. § 2.63(a)(2). The Government asserts that "[t]o the extent the patient files contain any 'communications' between the patients and Defendant and her office, such communication does not constitute 'confidential communications' for purposes of 42 C.F.R. § 2.63." Gov't's Opp'n 16. It further contends that the restrictions on confidential communications only relate to the diagnosis and treatment of substance use disorder. Gov't's Opp'n 16.

"Confidential communications" is not a defined term in the regulations, but 42 C.F.R. § 2.63 makes clear that it applies to "confidential communications made by a patient to a part 2 program in the course of diagnosis, treatment, or referral for treatment." 42 C.F.R. § 2.63(a). "Diagnosis means any reference to an individual's substance use disorder or to a condition which is identified as having been caused by

[9] Alternatively, the government could establish good cause and that "[t]he disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties." 42 C.F.R. § 2.63(a)(1).

that substance use disorder which is made for the purpose of treatment or referral for treatment." 42 C.F.R. § 2.11. "Treatment" is defined as "the care of a patient suffering from a substance use disorder . . . in order to reduce or eliminate the adverse effects upon the patient." *Id.* § 2.11. Accordingly, the protections for "confidential communications" extend only to diagnosis, treatment, or referral for treatment for substance use disorder, not other medical issues such as pain management.

At oral argument, the Government conceded that it did not seek an order to allow disclosure of "confidential communications" because it narrowly interpreted section 2.63 as only applying in situations where a patient makes some incriminatory statement to the doctor, such as about a crime the patient committed. The Government argued that to construe the regulation more broadly would hamstring the Government's ability to investigate programs that might be endangering the lives of patients and would be counter to the goals of the Act and its regulations. While that may be true, the plain language of 42 C.F.R. § 2.63 is broader than the Government's restricted interpretation.

At oral argument, the Defendant offered a list of pages from the patient records, which contain "communications made by a patient" to Dr. Norris in the course of diagnosis and treatment for substance use disorder. *See* Def.'s Hr'g Ex. 8. Overall, the records show that the primary purpose of the patients' visits to Dr. Norris was for treatment of *pain management*, not substance use disorder. *See, e.g.*, Def.'s Hr'g Ex. D1, at 011, 015, 023–026, 028, 062; Def.'s Hr'g Ex. D2, at 013; Def.'s Hr'g Ex. D3, at 001, 003; Def.'s Hr'g Ex. D4, at 030, 071, 073, 099, 231, 1042, 1374; Def.'s Hr'g

Ex. D5, at 002. But the records also reveal that all five of the patients suffer from or have suffered from substance use disorder. For example, the "problem" and "assessment" sections in the visit notes of Patients 1, 2, 4, and 5 contain communications that those patients made to Dr. Norris about their substance use disorder, such as how they are managing their addiction and recovery while being prescribed controlled substances for pain.[10] *See* Def.'s Hr'g Ex. D1, at 392; Def.'s Hr'g Ex. D2, at 460; Def.'s Hr'g Ex. D4, at 379; Def.'s Hr'g Ex. D5, at 142. The five pain management patients' communications about their addiction history and progress served the purpose of guiding Dr. Norris's decisions about how to treat their pain. Communications from a patient suffering from substance use disorder to a part 2 program can be "confidential communications" even if the primary purpose of the visit is pain management if the communications are made to reduce or eliminate the adverse effects of the substance use disorder on the patient.

The Government contends that it could have met the heightened standard required by 42 C.F.R. § 2.63 because Dr. Norris's prescription practices put people at risk of overdose death and serious bodily injury. Gov't's Opp'n 17. But the fact is that the Government did not seek such an order before it seized the patient records. To that extent, the Defendant has established that the Government violated 42 C.F.R. § 2.63.

[10] The file for Patient 3 contains even more direct communication about treatment of substance abuse disorder, including a page with quotes and narrative communications from the patient to Dr. Norris describing the patient's history with alcohol, programs, and meetings, in addition to notations that Dr. Norris gave Patient 3 the names of counselors and prescribed Naltrexone. Def.'s Hr'g Ex. D3, at 019.

3. Notice Requirements

The Defendant next argues that the Government violated the regulatory requirements pertaining to notification upon implementation of the Patient Records Orders. The Government essentially concedes this violation, but it counters that Dr. Norris has shown no prejudice from having received delayed notification and argues that suppression is not an appropriate remedy. *See* Gov't's Opp'n 17–18.

The regulatory notice requirements are found in 42 C.F.R. § 2.64(b) and 42 C.F.R. § 2.66(b). Section 2.64(b), which sets forth procedures for authorizing disclosures for noncriminal purposes, states:

> Notice. The patient and the person holding the records from whom disclosure is sought must be provided:
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> (1) Adequate notice in a manner which does not disclose patient identifying information to other persons; and
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> (2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order as described in § 2.64(d).[11]

42 C.F.R. § 2.64(b). Section 2.66(b), which provides procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or a person holding the records, states:

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[11] Section 2.64(d) sets forth the "criteria for entry of order" and provides:

> An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that: (1) Other ways of obtaining the information are not available or would not be effective; and (2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

42 C.F.R. § 2.64(d).

> Notice not required. An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the part 2 program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order in accordance with § 2.66(c).[12]

42 C.F.R. § 2.66(b).

The purpose of section 2.66(b) is limited—to provide the Defendant an opportunity to seek revocation or amendment based on "the statutory and regulatory criteria for the issuance of the court order in accordance with § 2.66(c)." 42 U.S.C. § 2.66(b); *see Shinderman*, 515 F.3d at 12. Once the Defendant became aware of the Patient Records Orders, she did not move to amend or revoke the Orders. Even at the most recent suppression hearing, the Defendant has not argued that good cause did not exist for the issuance of the Patient Records Orders. At least one court has held that a suppression hearing is an adequate opportunity to seek revocation or amendment of such an order. *See United States v. Bryant*, 849 F. App'x 565, 569, 572–73 (6th Cir. 2021) ("[The defendant] was afforded the opportunity to challenge the order at the suppression proceedings at the district court, and she does not explain how she was prejudiced by not receiving notice sooner.").

The Defendant argues that by the time she learned of the existence of the Patient Records Orders she had already been indicted, and she claims that contesting the Orders was futile. At oral argument, the Defendant pointed out that notice would

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12 42 C.F.R. § 2.66(c) refers back to the requirements of 42 C.F.R. § 2.64(d) and (e).

have given the Defendant an opportunity to insist that the Government adhere to the Orders, but the Defendant has never attempted to address the criteria for the issuance of the Patient Records Orders, i.e., that good cause for the Orders did not exist. *See* 42 C.F.R. §§ 2.66(b)–(c), 2.64(d)–(e). Accordingly, although the Defendant has established a violation of section 2.66(b), she has failed to establish that she was prejudiced by the delay in notification. *See Shinderman*, 515 F.3d at 12 ("[A]ny profession of prejudice would be undone by the defendant's failure to move under section 2.66(b) for revocation or amendment. After all, once the government notified him of the issuance of the disclosure orders, he had the opportunity to object to their validity and scope—yet he conspicuously failed to move for relief at that point.").

C. Whether Suppression Is a Remedy Under the Act or Its Regulations

The First Circuit has held that generally,

> a violation of federal or state law triggers the exclusionary rule only if the evidence sought to be excluded "arises directly out of statutory violations that implicate important Fourth and Fifth Amendment interests."

United States v. De La Cruz, 835 F.3d 1, 6 (1st Cir. 2016) (quoting *Sanchez-Llamas v. Oregon*, 548 U.S. 331, 348 (2006)). "[A] statutory violation 'untethered to the abridgment of constitutional rights' is insufficient to justify suppression.' " *Id.* (quoting *United States v. Adams,* 740 F.3d 40, 43 (1st Cir. 2014); *see also United States v. Pompy*, No. 18-cr-20454, 2021 WL 978797, at *5 (E.D. Mich. Mar. 16, 2021) (in the context of the Act, "the exclusionary rule deters constitutional violations, not violations of federal, state, or local regulations"). Given that cases of suppression for

statutory violations are "few," "for obvious reasons this is even more clearly true of regulations." *United States v. Henry*, 482 F.3d 27, 32 (1st Cir. 2007).

There is an exception to this general rule, however, where a statute or regulation expressly provides for a suppression remedy. *United States v. Li*, 206 F.3d 56, 61 (1st Cir. 2000) (en banc); *United States v. Smith*, No. 5-73-B-JAW, 2006 WL 47556, at *3 (D. Me. Jan. 6, 2006). The Defendant makes the argument that 42 C.F.R. § 2.13 provides an exclusionary remedy. Mot. to Suppress 12. Section 2.13 provides:

> The patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and *may not otherwise be disclosed or used in any . . . criminal . . . proceedings* . . . .

42 C.F.R. § 2.13(a) (emphasis added).

A similar argument was made in *United States v. Shinderman*, 515 F.3d 5 (1st Cir. 2008). There, the Government was investigating a methadone treatment clinic, and it sought and obtained three use and disclosure orders to allow substance use disorder patient records previously obtained during an administrative inquiry conducted by the Department of Health and Human Services to be disclosed to criminal investigators. *Shinderman*, 515 F.3d at 9–10. The Magistrate Judge who entered the use and disclosure orders also authorized the Government to defer providing the upon-implementation notice to the clinic as required under 42 C.F.R. § 2.66. *Id.* After the defendant was indicted, he moved to suppress the records, contending that the deferred notice violated the regulatory scheme and that the Act required suppression of records obtained in violation of the regulations. *United States*

v. Shinderman, No. CRIM. 05-67-P-H, 2006 WL 522105, at *9 (D. Me. Mar. 2, 2006), *R. & R. adopted as modified by* 432 F. Supp. 2d 149.

In her recommended decision in *Shinderman*, the Magistrate Judge concluded that there was no exclusionary remedy for a program or its medical staff who become targets or defendants in criminal proceedings. *Id.* at *10. Relying on the fact that section 290dd-2(c)(2) applies only to patients,[13] the Magistrate Judge wrote:

> To the extent that a blanket prohibition might be drawn from the statute against the use or introduction of a confidential record to advance a criminal investigation or prosecution, such a prohibition would exist, exclusively, for investigations or prosecutions targeting a patient. . . . Congress has not prescribed an exclusionary remedy for the benefit of programs or their employees who become targets in criminal investigations or defendants in criminal prosecutions.

Id.

The District Court adopted the Magistrate Judge's recommended decision but wrote: "Although the statute speaks only of fines for noncompliance, 42 U.S.C. § 290dd-2(f) (2000), and directs its attention to patients, *see, e.g.*, *id.* § 290dd-2(c), both the statute and the regulations contain broad language that would support suppression for at least some violations." *United States v. Shinderman,* 432 F. Supp. 2d 149, 151 (D. Me. 2006). The District Court found that the Government had violated the statute by delaying notice but concluded that "suppression [was] too drastic a remedy" because "[t]here was no bad faith (the government obtained court approval) and Shinderman has not shown prejudice from the delay[ed notice] alone." *Id.* at 154.

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[13] Section 290dd-2(c) provides: "[e]xcept as otherwise authorized by a court order . . . , a record . . . may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority, *against a patient*." 42 U.S.C. 290dd-2(c) (emphasis added).

On appeal, the First Circuit sidestepped the "potentially important questions anent the meaning of the regulations and the appropriate use of the exclusionary rule to address a regulatory infraction" because it concluded that the delayed notice did not constitute a regulatory violation. *Shinderman*, 515 F.3d at 12.

The Defendant, seizing on dicta from both the District Court and the First Circuit regarding the possibility of suppressing evidence to address a regulatory infraction, argues that exclusion of the records obtained by the Government in violation of the Act and its regulations is required. The Defendant contends that particularly where the Government's violations of the regulations were flagrant and repeated, suppression is warranted.

I agree with the Magistrate Judge in *Shinderman* that the Act's express prohibition against using substance use disorder patient records in a criminal proceeding is limited to criminal proceedings against a patient. Although, section 2.13 speaks broadly of prohibiting disclosure or use in "any" criminal proceeding, the purpose of the Act is "to protect people who are seeking treatment for their drug addiction" and the regulatory scheme focuses on protecting patients from having their records used against them, not on protecting doctors who may potentially be harming the patients. *See Pompy*, 2021 WL 978797, at *5; 42 C.F.R. § 2.2(b)(2) (stating that the purpose of the regulations is to "ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment"). A holistic reading of the regulations also

supports an interpretation that exclusion of records is limited to cases against patients. *See United States ex rel. Chandler v. Hektoen Inst. for Med. Rsch.*, No. 97 C 514, 2003 WL 22284199, at *3 (N.D. Ill. Oct. 2, 2003) (regulations must be read as a whole). Further, the statute and regulatory scheme mandate the imposition of fines for penalties.[14] 42 U.S.C. § 290dd-2(f), 42 C.F.R. § 2.3; *see Pompy*, 2021 WL 978797, at *5 ("Suppression of evidence in a criminal prosecution is not the contemplated remedy for violating the regulation—a fine is."). Finally, the Defendant has not provided any authority where a court suppressed patient records for a violation of the regulations when prosecuting a doctor for illegal drug distribution.

The First Circuit has instructed that: "Suppression of evidence is strong medicine, not to be dispensed casually." *Adams,* 740 F.3d at 43. As in *Shinderman*, I find that such a drastic remedy is not appropriate here. The Government did obtain an order for the use and disclosure of patient records and sought to amend it when the investigation turned to Dr. Norris's other practices. And the Defendant has not convinced me that the Government was not entitled to seize all of Dr. Norris's patient records when it executed the search warrants. The Government established probable cause that Dr. Norris was prescribing outside the usual course of medical practice. It was entitled to review her patient records for evidence of that crime.

[14] The Defendant makes the fair point that the penalties are toothless when the agency committing the violations is tasked with enforcing the penalty section, but a mechanism does exist to file a report against any violators of the regulations to the United States Attorney for the judicial district in which the violation occurs. 42 C.F.R. § 2.4.

That said, the Defendant has shown that the Government violated the regulations in two ways—by seizing confidential communications contained within the patient records and by providing delayed notice. First, as to the seizure, the Patient Records Order did not entitle the Government to the "confidential communications" within the Defendant's Patient Records Exhibits (Defendant's Hearing Exhibits D1 through D5). While this violation is serious, there is no evidence that the Government acted in bad faith. A review of the patient records reveals how complex the determination of whether something is a "confidential communication" can be. The five patients whose records the Government plans to use at trial were primarily receiving treatment for pain management, not substance use disorder. The Government nonetheless applied for a use and disclosure order. While there may have been better ways to handle the records, the Government's failure to obtain a separate confidential communications order, as required by 42 C.F.R. § 2.63, is not so drastic a violation as to require suppression.

Second, as for the notice violations, again, the Government could have done better. If the Government needed to delay notice when it implemented the Patient Records Order by executing the Elation Warrant, it could have sought Court approval. And there was no basis not to provide notice when the Government implemented the Patients Records Orders by executing the Practice Warrant because Dr. Norris was arrested that same day and there would have been no further need for secrecy. But here, again, I find no bad faith. SA Wengler credibly testified that the investigation was hectic and that the Strike Force was motivated to act swiftly

out of concern that patients could die of overdoses. The delayed notice of the implementation of the Patient Records Orders appears to have been an oversight. And the Defendant has not challenged the criteria for the issuance of the Patient Records Orders, and thus she has not demonstrated that she was prejudiced by the delayed notice.

Finally, the Defendant urges me to consider the sheer scope of the violations, contending that the Government seized confidential communications from thousands of patients. The Defendant offers no concrete evidence of the scope of the violations. She asks me to infer this from her claim that thousands of patient files were taken.[15] But, even accepting this assertion, she has done nothing to establish the number of patients who were being treated for alcohol or substance use disorder or to demonstrate that the records seized actually contained "confidential communications." In reopening the suppression hearing and calling the Defendant's attention to the fact that she bore the burden of proof, I offered the Defendant an opportunity to supplement the record. The Defendant provided only the five patient files that the Government seeks to admit at trial. She has failed to establish the vast scope of the alleged violations that she claims, so I reject this argument as well.

Altogether, then, the Defendant has not established that she is entitled to the drastic remedy of suppression for the Government's regulatory violations here. The

[15] To support this claim, the Defendant submitted a spreadsheet, which had every column and row redacted and which defense counsel contended was evidence that 2,040 patient files were seized pursuant to the Elation Warrant. Def.'s Hr'g Ex. 6.

Defendant also asserts that the regulatory violations constituted constitutional violations so I turn to those arguments next.

III. Violations of the Fourth Amendment

The Defendant contends that the Government's violations of the Patient Records Orders and the Act and its regulations made the seizure of patient records unreasonable under the Fourth Amendment. The Defendant also asserts a Fourth Amendment theory that the seizures exceeded the scope of the "items to be seized" articulated in the warrants. Def.'s Reply 6 (quoting *Horton v. California*, 496 U.S. 128, 140 (1990)). The Government contends that, to the extent there were violations of the regulations, they do not rise to the level of violations of the Fourth Amendment and suppressing the patient files and other evidence is not an appropriate remedy. Gov't's Opp'n 19.

The Fourth Amendment protects "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures," and provides that "no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the . . . things to be seized." U.S. Const. amend. IV. According to the Defendant, by referencing the Patient Records Orders in the affidavits in support of the Practice and Elation Warrants, the Government limited the records it could take. Def.'s Reply 6. But, as explained above, this argument is based on the faulty premise that the Government was limiting its investigation to Dr. Norris's prescription practices as they pertained to alcohol and substance use disorder patients. The Government was investigating Dr. Norris's prescription practices generally. Although the affidavit in support of the Elation

Warrant states that Dr. Norris has a specialty in addiction medicine and identified some red flags in Dr. Norris's prescribing practice for patients with substance use disorder, for the most part, it does not specify what type of patients received these prescriptions. *See* Aff. in Supp. of Search Warrant ¶¶ 45, 67 (Docket No. 2:22-mj-00166-KFW, No. 1-1). The Government was not required by the Elation Warrant or the reference to the Patient Records Order contained in the affidavit in support of the Elation Warrant to limit its investigation to only alcohol and substance use disorder patients.

The Act (and thus the Orders) only protect records if they relate to substance abuse. *See Rogers v. England*, 246 F.R.D. 1, 2–3 (D.D.C. 2007) (restrictions on disclosure only apply to information, "whether or not recorded," which "would identify a patient as an alcohol or drug abuser" and is "drug abuse information" or "alcohol abuse information" obtained by a federally assisted alcohol or drug abuse program. (quoting 42 C.F.R. § 2.12(a)(i)–(ii)); *Pletcher v. State*, 338 P.3d 953, 956–58 (Alaska Ct. App. 2014); *Beard v. City of Chicago*, No. 03 C 3527, 2005 WL 66074, at *5 (N.D. Ill. Jan. 10, 2005) (restrictions on disclosure apply only to records pertaining to substance abuse diagnosis or treatment, not records pertaining to treatment for conditions unrelated to substance abuse issues). Simply put, the Government did not need a use and disclosure order for patient records that do not identify a patient as having a substance abuse disorder, so any limitations imposed by the Orders did not apply to the records of other patients. And, if the Government did not violate the

Patient Records Orders by obtaining non-substance abuse patient records, it did not violate the Fourth Amendment on that basis, either.

To the extent the Defendant is arguing that taking records containing confidential communications of patients being treated for substance or alcohol use disorder exceeded the scope of the Elation and Practice Warrants, that argument is also flawed. Both the Elation Warrant and the Practice Warrant authorized the seizure of a wide range of patient records.[16] And while the affidavits in support of the warrants note the existence of the Patient Records Order, nowhere did the affidavits assert that the Patient Records Order imposed a limit on the items to be seized pursuant to the warrants.[17] Even though the agents seized confidential

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[16] Specifically, the Elation Warrant authorized the seizure of records including "[a]ll emails, communications, or messages to or from patients, or pertaining to patients," "all clinical files and patient records for all Medicare patients," and "[a]ll records showing the preparation of medical records, such as daily route sheets, partially completed forms, pre-printed forms, pre-signed blank forms, and evidence of the mailing or sharing of such documents with other persons or receipt of such documents from other persons for Medicare patients." Appl. for a Warrant 28–29, (Docket No. 2:22-mj-00166-KFW, ECF No. 1); Elation Warrant (Docket No. 2:22-mj-00166-KFW, ECF No. 2). Among other records, the Practice Warrant authorized the seizure of

> All records, regardless of when they were created, related in any way to the patients listed in Exhibit 1, including, without limitation, the following type of records: patient charts, files, records, superbills, invoices, treatment cards, prescription records, dispensing orders, patient ledger cards, patient complaints, patient sign-in sheets, provider notes, medical assistant and staff notes, certificates of medical necessity, diagnostic test notes or reports, original patient or referral source listings.

Appl. for a Warrant 38 (Docket No. 2:22-mj-00198-NT, ECF No. 10); Practice Warrant (Docket No. 2:22-mj-00198-NT, ECF No. 2). The warrant also authorized the seizure of "[a]ll correspondence, including memoranda, protocols, letters, and electronic mailings (emails) concerning any of the records described in the previous paragraphs." Appl. for a Warrant 40 (Docket No. 2:22-mj-00198-NT, ECF No. 10); Practice Warrant.

[17] This raises the interesting question, not addressed by the parties, of whether the records seized should have been screened and had confidential communications redacted, and, if so, by whom. Clearly the target of a criminal investigation is not given the opportunity to screen the records. On the other hand, the statutory and regulatory scheme protecting the confidentiality of the substance use disorder patient records does not countenance having a team of investigators comb through confidential communications between substance use disorder patients and their doctors in search of evidence that incriminates a target. The Government should have attempted to get a disclosure order for any

communications that were outside the scope of the Patient Records Orders, thereby violating those Orders and the 42 U.S.C. § 290dd-2 regulatory scheme, the seizure of those records did not exceed the scope of the Elation Warrant and the Practice Warrant.

Finally, the Defendant reasserts her argument that the magnitude of the violations made the seizure unreasonable under the Fourth Amendment. But the analysis above as to why suppression is too drastic a remedy to support exclusion under the Act applies equally to the argument that the magnitude of the violations made the search unreasonable under the Fourth Amendment. The Defendant has failed to establish the scope of the violations. And she offers no authority for the claim that statutory or regulatory violations automatically make a search based on a warrant unreasonable for Fourth Amendment purposes. If they did, it would eviscerate the general rule that statutory violations alone are insufficient to justify suppression. *De La Cruz*, 835 F.3d at 6.

IV. Violation of the Fifth Amendment

The Defendant also argues that suppression is required because the Government's failure to provide notice of the Patient Records Orders upon implementation constituted a violation of Dr. Norris's substantive and/or procedural due process rights under the Fifth Amendment. Mot. to Suppress 24. The only authority the Defendant offers for this proposition is a statement from the dissent in

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confidential communications or otherwise sought guidance from the court, as other parties have done. *See United States ex rel. Chandler v. Hektoen Inst. for Med. Rsch.*, No. 97 C 514, 2003 WL 22284199, at *8 (N.D. Ill. 2003) (discussing limiting the number of people with access or hiring a third party agreeable to both sides to screen records and redact confidential communications).

United States v. Caceres, 440 U.S. 741 (1979) that "one under investigation is legally entitled to insist upon the observance of rules promulgated by an executive or legislative body for his protection." *Caceres*, 440 U.S. at 757–58 (internal quotation omitted). The *Caceres* Court held, however, that tape recordings made by an IRS agent in violation of IRS electronic surveillance regulations should *not* be suppressed. *Id.* at 754–57. The Defendant does not meaningfully engage with *Caceres* or develop her Fifth Amendment argument, and it is likely waived on that basis, but my conclusion that Dr. Norris did have a meaningful opportunity to move to revoke and/or amend the Patients Records Orders and failed to exercise that opportunity proves fatal to her argument in any event.

V. Inherent Supervisory Powers

Finally, the Defendant argues that I should use my inherent supervisory powers to suppress all evidence of protected patient records. Mot. to Suppress 25–26. "[F]ederal courts may, within limits, formulate procedural rules not specifically required by the Constitution or the Congress." *United States v. Hasting*, 461 U.S. 499, 505 (1983). The purposes of the supervisory powers are "to implement a remedy for violation of recognized rights; to preserve judicial integrity by ensuring that a conviction rests on appropriate considerations validly before the jury; and finally, as a remedy designed to deter illegal conduct." *Id.* (internal citations omitted). In criminal cases, courts will consider unleashing their supervisory powers " 'when confronted with extreme misconduct and prejudice,' in order 'to secure enforcement of better prosecutorial practice and reprimand of those who fail to observe it.' " *United States v. Horn*, 29 F.3d 754, 760 (1st Cir. 1994) (quoting *United States v. Osorio*, 929

F.2d 753, 763 (1st Cir. 1991)). "Even so, courts must use these powers sparingly," and only when there is no effective alternative. *United States v. Stokes*, 124 F.3d 39, 46 (1st Cir. 1997) (internal quotation omitted); *see also Horn*, 29 F.3d at 760; *Chambers v. NASCO, Inc.*, 501 U.S. 32, 44 (1991). And suppression only excludes evidence taken in "willful disobedience of law." *United States v. Payner*, 447 U.S. 727, 735 & n.7 (1980).

This case is not appropriate for the use of the Court's supervisory powers. Even with the regulatory violations regarding confidential communications and notice, I see no prejudice to the Defendant's rights.

CONCLUSION

For the reasons stated above, the Court **DENIES** the Defendant's Motion to Suppress for Violation of Defendant's Fourth and Fifth Amendment Rights and Violation of Court Order for Disclosure and Use of Patient Records (ECF No. 71).

SO ORDERED.

/s/ Nancy Torresen
United States District Judge

Dated this 26th day of April, 2024.